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AMENDED IN ASSEMBLY MAY 3, 2004
AMENDED IN SENATE JANUARY 6, 2004
AMENDED IN SENATE MARCH 24, 2003

SENATE BILL

No. 142

Introduced by Senator Alpert
(Coauthors: Senators Kuehl and Speier)
(Coauthor: Assembly Member Lieber)

February 6, 2003

An act to amend Sections 124977, 124980, 125000, and 125001 of the Health and Safety Code, relating to genetic testing.

LEGISLATIVE COUNSEL'S DIGEST

SB 142, as amended, Alpert. Genetic testing.

(1) The Hereditary Disorders Act, among other provisions, declares the intent of the Legislature that the state's hereditary disorders program activities are to be fully supported by fees collected for services provided by the program, unless otherwise provided. Existing law requires the department to charge a fee to all payers for any tests or activities performed pursuant to provisions relating to genetic disorder prevention services, including the Hereditary Disorders Act. Existing law requires that any fee charged for screening and followup services provided to Medi-Cal eligible persons, health care service plan enrollees, or persons covered by disability insurance policies are to be paid directly to the Genetic Disease Testing Fund, a continuously appropriated fund, to be used for purposes of the Hereditary Disorders Act, subject to the terms and conditions of the applicable health care

service plan or insurance coverage. Under existing law, all moneys collected by the department pursuant to the act must be deposited into the fund. In addition, on and after July 1, 2002, the State Department of Health Services is required to charge a fee for newborn screening and followup services, and requires the amount of the fee to be established pursuant to regulation and periodically adjusted by the director.

This bill would make legislative findings and declarations with respect to the need for expanded genetic testing of newborns in California.

This bill would delete the requirement that the director establish and adjust the newborn screening fee. The bill would require the department to adopt regulations to implement the fee provisions, in consultation with the Department of Insurance and the Department of Managed Health Care.

~~This bill would provide for direct payment of fees into the Genetic Disease Testing Fund by persons eligible for the Healthy Families Program, and would delete the requirement that payment of fees into the fund would be subject to the terms and conditions of the health care service plan or insurance policy. The bill would require all hospital contracts for maternity care with public and private payers, except for certain Medi-Cal contracts, to be amended to ensure full payment to the hospital of the established fee amount.~~

~~This bill would provide that the imposition of a General Fund-based hiring freeze shall not apply to positions supported by the Genetic Disease Testing Fund that are necessary to implement expanded newborn screening, and that these positions shall also be exempt from provisions of existing law relating to the abolishment of vacant state positions.~~

(2) Existing law requires the Director of Health Services to establish necessary regulations and standards for hereditary disorders programs, in order to promote and protect the public health and safety. Existing law requires these standards to implement designated principles, including provisions for compensatory and civil damages for an individual whose confidentiality has been breached as a result of a violation of the Hereditary Disorders Act, as well as an award of attorney's fees and litigation costs.

This bill would revise the above provisions and would additionally provide for imprisonment, a fine, or both, for the knowing breach of confidentiality of an individual tested under the act. By creating a new crime, the bill would impose a state-mandated local program.



(3) Existing law requires the State Department of Health Services to establish a genetic disease unit to coordinate all departmental programs in the area of genetic disease. Existing law requires the genetic disease unit to evaluate and prepare recommendations on the implementation of tests for the detection of certain hereditary and congenital diseases.

This bill would add biotinidase disorders of fatty and organic acid metabolism to the diseases for which the genetic disease unit is required to evaluate and prepare recommendations.

This bill would require the department to expand statewide screening of newborns to include tandem mass spectrometry screening for fatty acid *oxidation*, *amino acid*, and organic acid disorders and congenital adrenal hyperplasia, and to provide information with respect to these disorders and testing resources to all women receiving prenatal care and admitted to a hospital for delivery. If the department is unable to provide statewide screening for these disorders by July 1, 2005, the bill would require the department to temporarily obtain statewide screening for these disorders from one or more laboratories, through a competitive bid process. The bill would also enact related reporting requirements.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) Birth defects are the leading cause of infant death in
4 California and the United States.

5 (b) In California, more than 530,000 babies are born each year.
6 According to the California Birth Defects Monitoring Program,
7 one in 33 will be born with a debilitating condition. Of these, one
8 in 11 will die.

9 (c) Each year, newborn screen programs in all states test four
10 million newborns to identify those who may have specific genetic
11 and metabolic disorders that could threaten their life or long-term

1 health and development. An estimated one in 3,000 newborn
2 children carries a metabolic disorder that interferes with the
3 growing child's development. California conducts newborn
4 screening for the following disorders: phenylketonuria,
5 galactosemia, sickle cell disease, and congenital hypothyroidism.
6 *Since 1980, more than 5,500 cases of these disorders have been*
7 *detected from a small blood sample collected from each newborn*
8 *shortly after birth.* Without early detection and dietary treatment,
9 children affected with these genetic conditions may suffer serious
10 illness, severe physical or developmental disability, and death. The
11 state's newborn screening program has proven effective in
12 reducing the incidence of morbidity and mortality resulting from
13 these four disorders.

14 (d) Recent technological advances make it possible and
15 affordable to screen for larger numbers of treatable metabolic
16 disorders, more than 20 from a single sample. At least 26 states
17 have implemented this new technology, tandem mass
18 spectrometry. After being the national leader for many years,
19 California has fallen far behind in its efforts to prevent infant
20 morbidity and mortality caused by treatable metabolic disorders.
21 At least 40 states now screen their newborns for more preventable
22 disorders than California.

23 (e) In 2002–03, the Genetic Disease Branch (GDB) of the State
24 Department of Health Services conducted a pilot project to expand
25 newborn screening to 30 disorders. ~~As a result of the pilot project,~~
26 ~~51 affected infants were identified and referred for treatment.~~
27 ~~Without expanded screening, these infants may have died or~~
28 ~~suffered severe disabilities, such as cerebral palsy, and required~~
29 ~~costly medical care, special education, developmental services,~~
30 ~~and physical, speech, or occupational therapies.~~

31 (f) ~~In California, the average annual cost of providing services~~
32 ~~to a person with a developmental disability is between fifteen~~
33 ~~thousand dollars (\$15,000) and one hundred fifty thousand dollars~~
34 ~~(\$150,000); special education costs are about seven thousand five~~
35 ~~hundred dollars (\$7,500) annually. According to the Centers for~~
36 ~~Disease Control and Prevention, the average lifetime cost of~~
37 ~~providing services to a child with mental retardation is one million~~
38 ~~fourteen thousand dollars (\$1,014,000). More than one half of all~~
39 ~~babies born in the state are eligible for Medi-Cal, most of these~~
40 ~~costs are borne by the state, and accordingly, significant costs are~~

~~also incurred by insurance companies, health maintenance organizations, and individual families.~~

(f) According to the Centers for Disease Control and Prevention, the average lifetime cost of providing services to a person with moderate mental retardation is \$1,014,000. For every 20 additional cases identified through expanded screening, average lifetime cost savings could exceed \$20,000,000. Approximately 38 percent of infants born in California are eligible for Medi-Cal. Thus, significant costs are incurred by the state for providing medical care, special education, developmental services, and physical and speech, or occupational therapies to children with untreated disorders. Health plans, insurance companies, and individual families also incur major costs.

(g) Cost-benefit analyses have repeatedly found that expanded newborn screening produces significant net benefits. The GDB estimates that for every dollar spent on expanded screening, two dollars and fifty-nine cents (\$2.59) is saved in average lifetime medical costs alone. ~~Taking into consideration special education and developmental services cost savings, the benefits are even greater.~~ costs. Moreover, expanded screening will save lives.

SEC. 2. Section 124977 of the Health and Safety Code is amended to read:

124977. (a) It is the intent of the Legislature that, unless otherwise specified, the program carried out pursuant to this chapter be fully supported from fees collected for services provided by the program.

(b) (1) The department shall charge a fee to all payers for any tests or activities performed pursuant to this chapter. The amount of the fee shall be established by regulation and periodically adjusted by the director in order to meet the ~~total~~ costs of this chapter. Notwithstanding any other provision of law, any fees charged for screening and followup services provided to persons ~~eligible~~ enrolled for the Medi-Cal program ~~or the Healthy Families Program~~, health care service plan enrollees, or persons covered by ~~disability~~ health insurance policies, shall be paid in full directly to the Genetic Disease Testing Fund. Notwithstanding any other provision of law, the department shall adopt regulations to implement this section, in consultation with the Department of Insurance and the Department of Managed Health Care.

1 (2) The department shall expeditiously undertake all steps
2 necessary to implement the fee collection process, including
3 personnel, contracts, and data processing, so as to initiate the fee
4 collection process at the earliest opportunity.

5 (3) Effective for services provided on and after July 1, 2002,
6 the department shall charge a fee to the hospital of birth, or, for
7 births not occurring in a hospital, to families of the newborn, for
8 newborn screening and followup services. The hospital of birth
9 and families of newborns born outside the hospital shall make
10 payment in full to the Genetic Disease Testing Fund.
11 Notwithstanding any other provision of law, hospital contracts for
12 maternity care with public and private payers, with the exception
13 of Medi-Cal contracts, *that do not provide for full payment to the*
14 *hospital of the amount established by regulation* shall be amended
15 to ensure full payment of the amount established by regulation to
16 the hospital. The department shall not charge or bill Medi-Cal
17 beneficiaries for services provided under this chapter.

18 (c) (1) The Legislature finds that timely implementation of
19 changes in genetic screening programs and continuous
20 maintenance of quality statewide services requires expeditious
21 regulatory and administrative procedures to obtain the most
22 cost-effective electronic data processing, hardware, software
23 services, testing equipment, and testing and followup services.

24 (2) The expenditure of funds from the Genetic Disease Testing
25 Fund for these purposes shall not be subject to Section 12102 of,
26 and Chapter 2 (commencing with Section 10290) of Part 2 of
27 Division 2 of, the Public Contract Code, or to Division 25.2
28 (commencing with Section 38070). The department shall provide
29 the Department of Finance with documentation that equipment
30 and services have been obtained at the lowest cost consistent with
31 technical requirements for a comprehensive high-quality
32 program.

33 (d) (1) The department may adopt emergency regulations in
34 accordance with Chapter 3.5 (commencing with Section 11340) of
35 Part 1 of Division 3 of Title 2 of the Government Code. For the
36 purposes of the Administrative Procedure Act, the adoption of
37 regulations shall be deemed an emergency and necessary for the
38 immediate preservation of the public peace, health and safety, or
39 general welfare. Notwithstanding Chapter 3.5 (commencing with
40 Section 11340) of Part 1 of Division 3 of Title 2 of the Government

Code, these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Section 11346.1 and Section 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing. The regulations shall become effective immediately upon filing by the Secretary of State. Regulations shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with Sections 11346.8 and 11346.9 of the Government Code or shall be repealed.

(2) The Office of Administrative Law shall provide for the printing and publication of these regulations in the California Code of Regulations. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the regulations adopted pursuant to this chapter shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.

(3) The Legislature finds and declares that the health and safety of California newborns is in part dependent on an effective and adequately staffed genetic disease program, the cost of which shall be supported by the fees generated by the program. ~~Notwithstanding any other provision of law, the imposition of a General Fund-based hiring freeze shall not apply to positions supported by the Genetic Disease Testing Fund that are necessary to implement expanded newborn screening. These positions shall also be exempt from Section 12439 of the Government Code.~~

SEC. 3. Section 124980 of the Health and Safety Code is amended to read:

124980. The director shall establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety. Standards shall include licensure of master level genetic counselors and doctoral level ~~clinical~~ geneticists. Regulations adopted shall implement the principles established in this section. These principles shall include, but not be limited to, the following:

(a) The public, especially communities and groups particularly affected by programs on hereditary disorders, should be consulted before any regulations and standards are adopted by the department.

(b) The incidence, severity, and treatment costs of each hereditary disorder and its perceived burden by the affected community should be considered and, where appropriate, state and national experts in the medical, psychological, ethical, social, and economic effects or programs for the detection and management of hereditary disorders shall be consulted by the department.

(c) Information on the operation of all programs on hereditary disorders within the state, except for confidential information obtained from participants in the programs, shall be open and freely available to the public.

(d) Clinical testing procedures established for use in programs, facilities, and projects shall be accurate, provide maximum information, and the testing procedures selected shall produce results that are subject to minimum misinterpretation.

(e) No test or tests may be performed on any minor over the objection of the minor's parents or guardian, nor may any tests be performed unless the parent or guardian is fully informed of the purposes of testing for hereditary disorders and is given reasonable opportunity to object to the testing.

(f) No testing, except initial screening for phenylketonuria (PKU) and other diseases that may be added to the newborn screening program, shall require mandatory participation, and no testing programs shall require restriction of childbearing, and participation in a testing program shall not be a prerequisite to eligibility for, or receipt of, any other service or assistance from, or to participate in, any other program, except where necessary to determine eligibility for further programs of diagnoses of or therapy for hereditary conditions.

(g) Pretest and posttest counseling services for hereditary disorders shall be available through the program or a referral source for all persons determined to be or who believe themselves to be at risk for a hereditary disorder. Genetic counseling shall be provided by a physician, a certified advanced practice nurse with a genetics specialty, or other appropriately trained licensed health care professional and shall be nondirective, shall emphasize informing the client, and shall not require restriction of childbearing.

(h) All participants in programs on hereditary disorders shall be protected from undue physical and mental harm, and except for initial screening for phenylketonuria (PKU) and other diseases

that may be added to newborn screening programs, shall be informed of the nature of risks involved in participation in the programs, and those determined to be affected with genetic disease shall be informed of the nature, and where possible the cost, of available therapies or maintenance programs, and shall be informed of the possible benefits and risks associated with these therapies and programs.

(i) All testing results and personal information generated from hereditary disorders programs shall be made available to an individual over 18 years of age, or to the individual's parent or guardian. If the individual is a minor or incompetent, all testing results that have positively determined the individual to either have, or be a carrier of, a hereditary disorder shall be given through a physician or other source of health care.

(j) All testing results and personal information from hereditary disorders programs obtained from any individual, or from specimens from any individual, shall be held confidential and be considered a confidential medical record except for information that the individual, parent, or guardian consents to be released, provided that the individual is first fully informed of the scope of the information requested to be released, of all of the risks, benefits, and purposes for the release, and of the identity of those to whom the information will be released or made available, except for data compiled without reference to the identity of any individual, and except for research purposes, provided that pursuant to Subpart A (commencing with Section 46.101) of Part 46 of Title 45 of the Code of Federal Regulations entitled "Basic HHS Policy for Protection of Human Subjects," the research has first been reviewed and approved by an institutional review board that certifies the approval to the custodian of the information and further certifies that in its judgment the information is of such potentially substantial public health value that modification of the requirement for legally effective prior informed consent of the individual is ethically justifiable.

(k) *A physician providing information to patients on expanded newborn screening shall disclose to the parent the physician's financial interest, if any, in the laboratory to which the patient is being referred.*

(l) An individual whose confidentiality has been breached as a result of any violation of the provisions of the Hereditary

1 Disorders Act, as defined in subdivision (b) of Section 27, may
2 recover compensatory and civil damages. *Any person who*
3 *negligently breaches the confidentiality of an individual tested*
4 *under this article shall be subject to civil damages of not more than*
5 *ten thousand dollars (\$10,000), reasonable attorney's fees, and the*
6 *costs of litigation.* Any person who knowingly breaches the
7 confidentiality of an individual tested under this article shall be
8 subject to payment of compensatory damages, and in addition,
9 may be subject to civil damages of fifty thousand dollars
10 (\$50,000), reasonable attorney's fees, and the costs of litigation ~~or~~
11 ~~imprisonment, or imprisonment in the county jail of not more than~~
12 ~~one year.~~ If the offense is committed under false pretenses, the
13 person may be subject to a fine of not more than one hundred
14 thousand dollars (\$100,000), imprisonment ~~of not more than five~~
15 ~~years in the county jail of not more than one year,~~ or both. If the
16 offense is committed with the intent to sell, transfer, or use
17 individually identifiable health information for commercial
18 advantage, personal gain, or malicious harm, the person may be
19 subject to a fine of not more than two hundred fifty thousand
20 dollars (\$250,000), imprisonment ~~of not more than 10 years in the~~
21 ~~county jail of not more than one year,~~ or both.

22 ~~(l)–~~

23 (m) “Genetic counseling” as used in this section shall not
24 include communications that occur between patients and
25 appropriately trained and competent licensed health care
26 professionals, such as physicians, registered nurses, and
27 physicians assistants who are operating within the scope of their
28 license and qualifications as defined by their licensing authority.

29 SEC. 4. Section 125000 of the Health and Safety Code is
30 amended to read:

31 125000. (a) It is the policy of the State of California to make
32 every effort to detect, as early as possible, phenylketonuria and all
33 other preventable heritable or congenital disorders leading to
34 mental retardation or physical defects.

35 The department shall establish a genetic disease unit, that shall
36 coordinate all programs of the department in the area of genetic
37 disease. The unit shall promote a statewide program of
38 information, testing, and counseling services and shall have the
39 responsibility of designating tests and regulations to be used in
40 executing this program.

1 The information, tests, and counseling for children shall be in
2 accordance with accepted medical practices and shall be
3 administered to each child born in California once the department
4 has established appropriate regulations and testing methods. The
5 information, tests, and counseling for pregnant women shall be in
6 accordance with accepted medical practices and shall be offered
7 to each pregnant woman in California once the department has
8 established appropriate regulations and testing methods. These
9 regulations shall follow the standards and principles specified in
10 Section 124980. The department may provide laboratory testing
11 facilities or contract with any laboratory that it deems qualified to
12 conduct tests required under this section. However,
13 notwithstanding Section 125005, provision of laboratory testing
14 facilities by the department shall be contingent upon the provision
15 of funding therefor by specific appropriation to the Genetic
16 Disease Testing Fund enacted by the Legislature. If moneys
17 appropriated for purposes of this section are not authorized for
18 expenditure to provide laboratory facilities, the department may
19 nevertheless contract to provide laboratory testing services
20 pursuant to this section and shall perform laboratory services,
21 including, but not limited to, quality control, confirmatory, and
22 emergency testing, necessary to ensure the objectives of this
23 program.

24 (b) The department shall charge a fee for any tests performed
25 pursuant to this section. The amount of the fee shall be established
26 and periodically adjusted by the director in order to meet the costs
27 of this section.

28 (c) The department shall inform all hospitals or physicians and
29 surgeons, or both, of required regulations and tests and may alter
30 or withdraw any of these requirements whenever sound medical
31 practice so indicates. *To the extent practicable, the department*
32 *shall provide notice to hospitals and other payers in advance of*
33 *any increase in the fees charged for the program.*

34 (d) This section shall not apply if a parent or guardian of the
35 newborn child objects to a test on the ground that the test conflicts
36 with his or her religious beliefs or practices.

37 (e) The genetic disease unit is authorized to make grants or
38 contracts or payments to vendors approved by the department for
39 all of the following:

40 (1) Testing and counseling services.

1 (2) Demonstration projects to determine the desirability and
2 feasibility of additional tests or new genetic services.

3 (3) To initiate the development of genetic services in areas of
4 need.

5 (4) To purchase or provide genetic services from any sums as
6 are appropriated for this purpose.

7 (f) The genetic disease unit shall evaluate and prepare
8 recommendations on the implementation of tests for the detection
9 of hereditary and congenital diseases, including, but not limited to,
10 biotinidase ~~disorders of fatty and organic acid metabolism,~~
11 ~~deficiency and~~ cystic fibrosis, ~~and congenital adrenal hyperplasia.~~

12 The genetic disease unit shall also evaluate and prepare
13 recommendations on the availability and effectiveness of
14 preventative followup interventions, including the use of
15 specialized medically necessary dietary products.

16 It is the intent of the Legislature that funds for the support of the
17 evaluations and recommendations required pursuant to this
18 subdivision, and for the activities authorized pursuant to
19 subdivision (e), shall be provided in the annual Budget Act
20 appropriation from the Genetic Disease Testing Fund.

21 (g) Health care providers that contract with a prepaid group
22 practice health care service plan that annually has at least 20,000
23 births among its membership, may provide, without contracting
24 with the department, any or all of the testing and counseling
25 services required to be provided under this section or the
26 regulations adopted pursuant thereto, if the services meet the
27 quality standards and adhere to the regulations established by the
28 department and the plan pays that portion of a fee established
29 under this section that is directly attributable to the department's
30 cost of administering the testing or counseling service and to any
31 required testing or counseling services provided by the state for
32 plan members. The payment by the plan, as provided in this
33 subdivision, shall be deemed to fulfill any obligation the provider
34 or the provider's patient may have to the department to pay a fee
35 in connection with the testing or counseling service.

36 (h) The department may appoint experts in the area of genetic
37 screening, including, but not limited to, cytogenetics, molecular
38 biology, prenatal, specimen collection, and ultrasound to provide
39 expert advice and opinion on the interpretation and enforcement
40 of regulations adopted pursuant to this section. These experts shall

be designated agents of the state with respect to their assignments. These experts shall receive no salary, but shall be reimbursed for expenses associated with the purposes of this section. All expenses of the experts for the purposes of this section shall be paid from the Genetic Disease Testing Fund.

SEC. 5. Section 125001 of the Health and Safety Code is amended to read:

~~125001. (a) The Legislature finds and declares as follows:~~

~~(1) California requires testing at birth for certain genetic diseases or conditions.~~

~~(2) Technology called tandem mass spectography is now available that would permit testing for many more genetic diseases or conditions.~~

~~(b)~~

125001. (a) The department shall establish a program for the development, provision, and evaluation of genetic disease testing, and may provide laboratory testing facilities or make grants to, contract with, or make payments to, any laboratory that it deems qualified and cost-effective to conduct testing or with any metabolic specialty clinic to provide necessary treatment with qualified specialists. The program shall provide genetic screening and followup services for persons who have the screening.

~~(c)~~

(b) The department shall expand statewide screening of newborns to include tandem mass spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders and congenital adrenal hyperplasia as soon as possible. The department shall provide information with respect to these disorders and testing resources available, to all women receiving prenatal care and to all women admitted to a hospital for delivery. If the department is unable to provide this statewide screening by July 1, 2005, the department shall temporarily obtain these testing services through a competitive bid process from one or more public or private laboratories that meet the department's requirements for testing, quality assurance, and reporting. If the department determines that contracting for these services is more cost-effective, and meets the other requirements of this chapter, than purchasing the tandem mass spectrometry equipment themselves, the department shall contract with one or more public or private laboratories.

1 ~~(d)~~—

2 (c) The department shall report to the Legislature regarding the
3 progress of the program on or before July 1, 2006. The report shall
4 include the costs for screening, followup, and treatment as
5 compared to costs and morbidity averted for each condition tested
6 for in the program.

7 SEC. 6. No reimbursement is required by this act pursuant to
8 Section 6 of Article XIII B of the California Constitution because
9 the only costs that may be incurred by a local agency or school
10 district will be incurred because this act creates a new crime or
11 infraction, eliminates a crime or infraction, or changes the penalty
12 for a crime or infraction, within the meaning of Section 17556 of
13 the Government Code, or changes the definition of a crime within
14 the meaning of Section 6 of Article XIII B of the California
15 Constitution.

